510(K) SUMMARY

A. Submitter Information

Manufacturer: Medos International Sárl
Chemin-Blanc 38
2400 Le Locle, Switzerland

Submitter: DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02767

Contact Person: Kirsten Lehmuller
325 Paramount Drive
Raynham, MA 02767

Telephone number: 508-828-3291
Fax number: 508-828-3797
Email: klehmull@its.jnj.com

AUG 2 2 2013

B. Date Prepared July 25, 2013

C. Device Name

Trade/Proprietary Name: MOUNTAINEER® OCT Spinal System

Common/Usual Name: Spinal System

Classification Name: Spinal interlaminar fixation orthosis
per 21 CFR §888.3050
Pedicle screw spinal system
per 21 CFR §888.3070

D. Predicate Device Name

Trade name: MOUNTAINEER® OCT Spinal System (K041203, K042508, K080828, and K110353)

E. Device Description

The MOUNTAINEER® OCT Spinal System consists of plates, nuts, bone screws, rods, transverse rod connectors, lateral offset connectors, head-to-head connectors, cable connectors, dual wedding band and axial connectors, set screws, minipolyaxial screws, monoaxial screws, hooks, and SONGER® Cables. The components are manufactured from Titanium Alloy.

The MOUNTAINEER® OCT Spinal System Longitudinal rods are also available in cobalt-chromium-molybdenum alloy conforming to ASTM F-1537. Cobalt-chromium-molybdenum alloy rods are intended for use with titanium components only.

F. Intended Use

The MOUNTAINEER OCT Spinal System is intended to promote fusion of the cervical spine and occipitocervico-thoracic junction (occiput-T3), and is indicated for the following:

- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal stenosis
- Fracture/dislocation
- Atlanto/axial fracture with instability
- Occipitocervical dislocation
- Revision of previous cervical spine surgery
- Tumors

The occipital bone screws are limited to occipital fixation only.

The use of the monoaxial and polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

The SONGER® wire/cable system to be used with the MOUNTAINEER® OCT Spinal System allows for wire/cable attachment to the posterior cervical spine.

The MOUNTAINEER OCT Spinal System can also be linked to the ISOLA, MONARCH, MOSS MIAMI, VIPER and EXPEDIUM systems using the dual wedding band and axial connectors, and via dual diameter rods.

F. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use

The proposed modifications to the MOUNTAINEER® OCT Spinal System is identical to the predicate devices (K041203, K042508, K080828, and K110353) except for the proposed devices will be terminally sterilized via gamma radiation. The design, materials, indications, and technology remain identical to the predicate systems.

G. Materials

Manufactured from ASTM F-136 implant grade titanium alloy and ASTM F-1537 cobalt-chromium-molybdenum alloy.

H. Performance Data

Performance data is not provided in this submission.

I. Conclusion

The Substantial Equivalence Justification demonstrates that the devices are as safe, as effective, and perform as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 22, 2013

Medos International Sárl
% Ms. Kirsten Lehmuller
DePuy Spine, Incorporated
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K132332
Trade/Device Name: Mountaineer® OCT Spinal System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP, MNI
Dated: July 25, 2013
Received: July 26, 2013

Dear Ms. Lehmuller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K132332

Device Name: MOUNTAINEER® OCT Spinal System
Indications For Use:

The MOUNTAINEER OCT Spinal System is intended to promote fusion of the cervical spine and occipitocervico-thoracic junction (occiput-T3), and is indicated for the following:

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Prescription Use ___X___ AND/OR Over-The-Counter Use ___ ___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K132332